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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/661,086	09/12/2003	Jorg Thommes	037003-0305940	6600

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EXAMINER

THERKORN, ERNEST G

ART UNIT	PAPER NUMBER
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1723

DATE MAILED: 03/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/661,086

Applicant(s)

THOMMES ET AL.

Examiner

Ernest G. Therkorn

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 March 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-6 and 31-67 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-6 and 31-67 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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The amendment filed March 13, 2006 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: "the contents of which are incorporated herein by reference in their entirety."

Applicant is required to cancel the new matter in the reply to this Office Action.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3-5, and 31-33 are rejected under 35 U.S.C. 102(B) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Gottschlich (J. Chromatogr. A, 1997, 765(2):201-206). The claims are considered to read on Gottschlich (J. Chromatogr. A, 1997, 765(2):201-206). However, if a difference exists between the claims and Gottschlich (J. Chromatogr. A, 1997, 765(2):201-206), it would reside in optimizing the steps of Gottschlich (J. Chromatogr. A, 1997, 765(2):201-206). It would have been obvious to optimize the steps of Gottschlich (J. Chromatogr. A, 1997, 765(2):201-206) to enhance separation.

Claims 1, 3-4, 36-44, 46, 48, 51-54, 56, 58, and 62-67 are rejected under 35 U.S.C. 102(B) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Fulton, Presentation at Recovery of Biological Products X, Cancun, Mexico (June 2001). The claims are considered to read on Fulton, Presentation at Recovery of Biological Products X, Cancun, Mexico (June 2001). However, if a difference exists between the claims and Fulton, Presentation at Recovery of Biological Products X, Cancun, Mexico (June 2001), it would reside in optimizing the steps of Fulton, Presentation at Recovery of Biological Products X, Cancun, Mexico (June 2001). It would have been obvious to optimize the steps of Fulton, Presentation at Recovery of Biological Products X, Cancun, Mexico (June 2001) to enhance separation.

Claims 5, 31-33, 49, 50, 59, and 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fulton, Presentation at Recovery of Biological Products X, Cancun, Mexico (June 2001) in view of Gottschlich (J. Chromatogr. A, 1997, 765(2):201-206). At best, the claims differ from Fulton, Presentation at Recovery of Biological Products X, Cancun, Mexico (June 2001) in reciting separating an immunoglobulin with Protein A or Protein G. Gottschlich (J. Chromatogr. A, 1997, 765(2):201-206) on page 202 discloses IgG is purified with Protein A as a support in a simulated moving bed. It would have been obvious to separate an immunoglobulin with Protein A or Protein G because Gottschlich (J. Chromatogr. A, 1997, 765(2):201-206) on page 202 discloses IgG is purified with Protein A as a support in a simulated moving bed.

Claims 6 and 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gottschlich (J. Chromatogr. A, 1997, 765(2):201-206) as applied to claims 1, 3-5, and

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31-33 above, and further in view of Garrone (U.S. Patent No. 5,959,085). At best, the claims differ from Gottschlich (J. Chromatogr. A, 1997, 765(2):201-206) in reciting use of an acidic buffer. Garrone (U.S. Patent No. 5,959,085) (column 8, lines 55-60) discloses that an acidic buffer is an appropriate buffer for removing an antibody from a column. It would have been obvious to use an acidic buffer in Gottschlich (J. Chromatogr. A, 1997, 765(2):201-206) because Garrone (U.S. Patent No. 5,959,085) (column 8, lines 55-60) discloses that an acidic buffer is an appropriate buffer for removing an antibody from a column.

Claims 6 and 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fulton, Presentation at Recovery of Biological Products X, Cancun, Mexico (June 2001) in view of Gottschlich (J. Chromatogr. A, 1997, 765(2):201-206) as applied to claims 5, 31-33, 49, 50, 59, and 60 above, and further in view of Garrone (U.S. Patent No. 5,959,085). At best, the claims differ from Fulton, Presentation at Recovery of Biological Products X, Cancun, Mexico (June 2001) in view of Gottschlich (J. Chromatogr. A, 1997, 765(2):201-206) in reciting use of an acidic buffer. Garrone (U.S. Patent No. 5,959,085) (column 8, lines 55-60) discloses that an acidic buffer is an appropriate buffer for removing an antibody from a column. It would have been obvious to use an acidic buffer in Fulton, Presentation at Recovery of Biological Products X, Cancun, Mexico (June 2001) in view of Gottschlich (J. Chromatogr. A, 1997, 765(2):201-206) because Garrone (U.S. Patent No. 5,959,085) (column 8, lines 55-60) discloses that an acidic buffer is an appropriate buffer for removing an antibody from a column.

Claims 34-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Gottschlich (J. Chromatogr. A, 1997, 765(2):201-206) or Fulton, Presentation at Recovery of Biological Products X, Cancun, Mexico (June 2001) in view of Jiang (U.S. Patent No. 6,479,300) and Travis (U.S. Patent No. 4,016,149). At best, the claims differ from either Gottschlich (J. Chromatogr. A, 1997, 765(2):201-206) or Fulton, Presentation at Recovery of Biological Products X, Cancun, Mexico (June 2001) in reciting use of a urea regeneration buffer. Jiang (U.S. Patent No. 6,479,300) (column 4, lines 42-48) discloses the use of urea in buffers permits problem free operations. Travis (U.S. Patent No. 4,016,149) (column 10, lines 40-46) discloses that urea is a regenerating agent. It would have been obvious to use urea as a regenerating buffer in either Gottschlich (J. Chromatogr. A, 1997, 765(2):201-206) or Fulton, Presentation at Recovery of Biological Products X, Cancun, Mexico (June 2001) because Jiang (U.S. Patent No. 6,479,300) (column 4, lines 42-48) discloses the use of urea in buffers permits problem free operations and Travis (U.S. Patent No. 4,016,149) (column 10, lines 40-46) discloses that urea is a regenerating agent.

Claims 36-44, 46, 48-54, 56, 58-60, and 62-67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gottschlich (J. Chromatogr. A, 1997, 765(2):201-206) in view of Fulton, Presentation at Recovery of Biological Products X, Cancun, Mexico (June 2001). At best, claims 36, 37, 46, and 56 differ from Gottschlich (J. Chromatogr. A, 1997, 765(2):201-206) in reciting cleaning in place and claims 38-44, 48-54, 58-60, and 62-67 differ from Gottschlich (J. Chromatogr. A, 1997, 765(2):201-206) in reciting use of multiple washes. Fulton, Presentation at Recovery of Biological

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Products X, Cancun, Mexico (June 2001) page 22 discloses the use of cleaning in place for the obvious purpose of not moving the beads and on page 16 discloses use of multiple wash buffers for the obvious purpose of removing impurities. It would have been obvious to clean in place and use multiple washes in Gottschlich (J. Chromatogr. A, 1997, 765(2):201-206) because Fulton, Presentation at Recovery of Biological Products X, Cancun, Mexico (June 2001) page 22 discloses the use of cleaning in place for the obvious purpose of not moving the beads and on page 16 discloses use of multiple wash buffers for the obvious purpose of removing impurities.

Claims 37, 47, and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gottschlich (J. Chromatogr. A, 1997, 765(2):201-206) in view of Fulton, Presentation at Recovery of Biological Products X, Cancun, Mexico (June 2001) as applied to claims 36-44, 46, 48-54, 56, 58-60, and 62-67 above, and further in view of each of Abbott (U.S. Patent No. 4,430,496) and Yoshizako (U.S. Patent No. 6,641,735). At best, the claims differ from Gottschlich (J. Chromatogr. A, 1997, 765(2):201-206) in view of Fulton, Presentation at Recovery of Biological Products X, Cancun, Mexico (June 2001) in reciting use of an acid. Abbott (U.S. Patent No. 4,430,496) (column 6, lines 26-30) washing with phosphoric acid cleans the packing. Yoshizako (U.S. Patent No. 6,641,735) (column 8, lines 13-18) discloses that phosphoric acid buffer is a washing agent for the obvious purpose of cleaning. It would have been obvious to use acid in Gottschlich (J. Chromatogr. A, 1997, 765(2):201-206) in view of Fulton, Presentation at Recovery of Biological Products X, Cancun, Mexico (June 2001) either because Abbott (U.S. Patent No. 4,430,496) (column 6, lines 26-30)

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washing with phosphoric acid cleans the packing or because Yoshizako (U.S. Patent No. 6,641,735) (column 8, lines 13-18) discloses that phosphoric acid buffer is a washing agent for the obvious purpose of cleaning.

Claims 37, 47, and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fulton, Presentation at Recovery of Biological Products X, Cancun, Mexico (June 2001) in view of each of Abbott (U.S. Patent No. 4,430,496) and Yoshizako (U.S. Patent No. 6,641,735). At best, the claims differ from Fulton, Presentation at Recovery of Biological Products X, Cancun, Mexico (June 2001) in reciting use of an acid. Abbott (U.S. Patent No. 4,430,496) (column 6, lines 26-30) washing with phosphoric acid cleans the packing. Yoshizako (U.S. Patent No. 6,641,735) (column 8, lines 13-18) discloses that phosphoric acid buffer is a washing agent for the obvious purpose of cleaning. It would have been obvious to use acid in Fulton, Presentation at Recovery of Biological Products X, Cancun, Mexico (June 2001) either because Abbott (U.S. Patent No. 4,430,496) (column 6, lines 26-30) washing with phosphoric acid cleans the packing or because Yoshizako (U.S. Patent No. 6,641,735) (column 8, lines 13-18) discloses that phosphoric acid buffer is a washing agent for the obvious purpose of cleaning.

Claims 45 and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fulton, Presentation at Recovery of Biological Products X, Cancun, Mexico (June 2001) in view of Jiang (U.S. Patent No. 6,479,300) and Travis (U.S. Patent No. 4,016,149). At best, the claims differ from Fulton, Presentation at Recovery of Biological Products X, Cancun, Mexico (June 2001) in reciting use of a urea

regeneration buffer. Jiang (U.S. Patent No. 6,479,300) (column 4, lines 42-48) discloses the use of urea in buffers permits problem free operations. Travis (U.S. Patent No. 4,016,149) (column 10, lines 40-46) discloses that urea is a regenerating agent. It would have been obvious to use urea as a regenerating buffer in Fulton, Presentation at Recovery of Biological Products X, Cancun, Mexico (June 2001) because Jiang (U.S. Patent No. 6,479,300) (column 4, lines 42-48) discloses the use of urea in buffers permits problem free operations and Travis (U.S. Patent No. 4,016,149) (column 10, lines 40-46) discloses that urea is a regenerating agent.

Claims 45 and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gottschlich (J. Chromatogr. A, 1997, 765(2):201-206) in view of Fulton, Presentation at Recovery of Biological Products X, Cancun, Mexico (June 2001) as applied to claims 36-44, 46, 48-54, 56, 58-60, and 62-67 above, and further in view of Jiang (U.S. Patent No. 6,479,300) and Travis (U.S. Patent No. 4,016,149). At best, the claims differ from Gottschlich (J. Chromatogr. A, 1997, 765(2):201-206) in view of Fulton, Presentation at Recovery of Biological Products X, Cancun, Mexico (June 2001) in reciting use of a urea regeneration buffer. Jiang (U.S. Patent No. 6,479,300) (column 4, lines 42-48) discloses the use of urea in buffers permits problem free operations. Travis (U.S. Patent No. 4,016,149) (column 10, lines 40-46) discloses that urea is a regenerating agent. It would have been obvious to use urea as a regenerating buffer in Gottschlich (J. Chromatogr. A, 1997, 765(2):201-206) in view of Fulton, Presentation at Recovery of Biological Products X, Cancun, Mexico (June 2001) because Jiang (U.S. Patent No. 6,479,300) (column 4, lines 42-48) discloses the use of urea in buffers

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permits problem free operations and Travis (U.S. Patent No. 4,016,149) (column 10, lines 40-46) discloses that urea is a regenerating agent.

Claims 37, 47, and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gottschlich (J. Chromatogr. A, 1997, 765(2):201-206) in view of Fulton, Presentation at Recovery of Biological Products X, Cancun, Mexico (June 2001) as applied to claims 36-44, 46, 48-54, 56, 58-60, and 62-67 above, and further in view of each of Abbott (U.S. Patent No. 4,430,496) and Yoshizako (U.S. Patent No. 6,641,735). At best, the claims differ from Gottschlich (J. Chromatogr. A, 1997, 765(2):201-206) in view of Fulton, Presentation at Recovery of Biological Products X, Cancun, Mexico (June 2001) in reciting use of an acid. Abbott (U.S. Patent No. 4,430,496) (column 6, lines 26-30) washing with phosphoric acid cleans the packing. Yoshizako (U.S. Patent No. 6,641,735) (column 8, lines 13-18) discloses that phosphoric acid buffer is a washing agent for the obvious purpose of cleaning. It would have been obvious to use acid in Gottschlich (J. Chromatogr. A, 1997, 765(2):201-206) in view of Fulton, Presentation at Recovery of Biological Products X, Cancun, Mexico (June 2001) either because Abbott (U.S. Patent No. 4,430,496) (column 6, lines 26-30) washing with phosphoric acid cleans the packing or because Yoshizako (U.S. Patent No. 6,641,735) (column 8, lines 13-18) discloses that phosphoric acid buffer is a washing agent for the obvious purpose of cleaning.

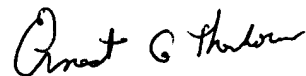
The remarks have been considered but are not deemed to be pertinent in view of the new grounds of rejection necessitated by applicants' amendment.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication should be directed to E. Therkorn at telephone number (571) 272-1149. The official fax number is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Ernest G. Therkorn
Primary Examiner
Art Unit 1723

EGT
March 24, 2006